

A61 - CALA Traceability Policy
Revision 2.13 - March 2011



CALA

Laboratory Accreditation

TABLE OF CONTENTS

TABLE OF CONTENTS	1
CALA TRACEABILITY POLICY	2
1.0 SCOPE	2
2.0 BACKGROUND	2
3.0 POLICY	2
4.0 CALA SPECIFIC REQUIREMENTS	3
4.1 Calibrations	3
4.1.1 External Calibrations.....	3
4.1.2 Internal Calibrations	3
4.2 Verifications	4
4.2.1 Balances.....	5
4.2.2 Mechanical Pipettes/Dispensers/Dilutors	5
4.2.3 Syringes	5
5.0 REFERENCES	5
APPENDIX A: GUIDANCE	6
A.1 Uncertainty and Traceability.....	6
A.2 Need for Traceability	7
A.2.1 What does traceability look like?	8
A.3 Implementation of this Policy in Accredited Laboratories	9
A.3.1 The Significance Test	9
A.3.2 Balances.....	11
A.3.3 Thermometers.....	12
A.3.4 Volumetric Measurements.....	12
A.3.5 Selecting a Calibration Laboratory	13
A.3.6 If an Accredited Calibration Laboratory is not Available for Specific Measurements	15
APPENDIX B: TERMS AND DEFINITIONS	16

CALA TRACEABILITY POLICY

1.0 SCOPE

This CALA Policy documents the requirements for accredited laboratories to maintain accreditation to ISO/IEC 17025 with regard to traceability of measurement. This policy applies to all laboratories accredited under the CALA Accreditation Program.

2.0 BACKGROUND

In order for users of laboratory data to have confidence in that data, they seek comfort that the values reported from one laboratory are the same as those reported from another laboratory in the same country, and the same as the values reported in another country. This is especially critical for testing performed to determine conformance to a specific criterion (e.g., lead in drinking water). This comparability is obtained through traceability.

Traceability is obtained by comparisons of measuring equipment in the laboratory to a national measurement laboratory (e.g., NRC or NIST). These comparisons typically involve a series of comparisons, each one performed under tightly controlled conditions, and each one involving a full accounting of the uncertainty at each step.

For most analytical testing laboratories, the three most common measurements that require traceability are mass (e.g., balances), temperature (e.g., thermometers), and volume (e.g., pipettes, dilutors and dispensers).

Clauses 5.6.2.1 and 5.6.2.2 of ISO/IEC 17025 require that all measurements that are a significant contributor to overall uncertainty of the test must be traceable to the SI (e.g., kg, °C and L).

3.0 POLICY

All measuring equipment that is a significant contributor to overall test uncertainty for accredited tests, shall be traceable to the SI through a National Metrology Institute (NMI) via an unbroken chain of comparisons.

Specifically, this means that:

- Accredited laboratories shall acquire instrument calibration services from only those service providers who have demonstrated technical competence in the propagation of uncertainties through instrument calibration;

- Accredited laboratories shall acquire reference materials from only those reference material providers deemed competent in the derivation of the uncertainties associated with these reference materials; and,
- Accredited laboratories may undertake the propagation of uncertainties for their own working instruments provided:
 - The laboratory has documented procedures for this task;
 - The laboratory reference instrument from which traceability is derived, has been calibrated in accordance with 2 above; and
 - The laboratory staff has received documented training in the propagation of uncertainties from the reference device to the working instrument.

4.0 CALA SPECIFIC REQUIREMENTS

4.1 Calibrations

Laboratories that calibrate their measurement equipment on an annual basis are deemed to be compliant with this policy. Decreasing the frequency of calibration will save the laboratory some calibration costs, but this can only be done if the laboratory has solid evidence in hand about how each instrument contributes to the overall uncertainties of all measurements made with it (see A.3.1 Significance Test in appendix A for an example). Conversely, it may be possible that the frequency of calibration needs to be increased (e.g., semi-annually, quarterly, or monthly). Calibration can be achieved by external calibration services or by internal calibration.

4.1.1 External Calibrations

When using an external calibration service to comply with this policy, the calibration laboratory used must be accredited to ISO/IEC 17025 and provide an appropriate calibration certificate. When looking at the calibration certificate the following things should appear on the certificate:

- A statement that that calibration laboratory is accredited to ISO/IEC 17025;
- The serial number of the measuring equipment being used to calibrate your equipment and a statement that the measuring equipment is traceable to SI units through an NMI; and,
- The measurement range for which your equipment was calibrated and the specific uncertainty measurements for that range.

If newly purchased measurement equipment is not provided with an appropriate calibration certificate, which is still common for many pieces of dispensing equipment, then a calibration must be performed prior to use.

4.1.2 Internal Calibrations

A laboratory may perform it's own calibrations as long as it follows an acceptable calibration procedures such as:

- For Balances: NISTIR 6919 – Recommended Guide for Determining and Reporting Uncertainties for Balances and Scales;
- For Thermometers: NIST Special Publication 1088 – Maintenance, Validation and Recalibration of Liquid-in-Glass Thermometers; or,
- For Mechanical Pipettes/Dispensers/Dilutors: generally accepted procedures such as those provided by Troemner, Mettler-Toledo, and Rainin.

Laboratories that perform their own calibrations must document the calibration procedure and must demonstrate:

- that the person conducting the calibration has been properly trained on the procedure used;
- that they can competently propagate uncertainties from the reference standard to the working instrument; and,
- that the calibrations have statistically established acceptance criteria and take appropriate action when these conditions are not met.
- For Balances:
 - that they use calibration weights that have been calibrated by a laboratory accredited to ISO/IEC 17025 for this purpose. The calibration weights must be recalibrated at a frequency consistent with 4.1 above.
- For Thermometers:
 - that they use reference thermometers that have been calibrated by a laboratory accredited to ISO/IEC 17025 for this purpose. The reference thermometers must be recalibrated at a frequency consistent with 4.1 above.
- For Mechanical Pipettes/Dispensers/Dilutors/Large volume syringes:
 - traceability is obtained through repeated measurements on a calibrated balance. For adjustable dispensing devices, this procedure is performed at more than one volume.
 - Class A glassware does not require calibration unless over-heated or chipped, for most methods typically used by environmental testing laboratories.

4.2 Verifications

Instruments that drift, or are prone to sudden changes in precision or measurement capability, require periodic verification. Affected equipment will include, but may not be limited to, balances, mechanical pipettes and portable thermocouples.

For these types of sensitive instruments, the laboratory must have verification procedures that detail:

- The frequency of verifications. If a frequency less than daily (when in use) is used, the selected frequency must be such that there is no risk of suspect data being released to customers. There may be instances, such as use under adverse conditions, when a frequency greater than daily may be required;

- The acceptance criteria and if the acceptance criteria are not met, the incident is treated as a non-conformance, investigated and a corrective action implemented (e.g., re-calibration or replacement).

4.2.1 Balances

The as-used verification is performed using a minimum of two weights that are within the weights typically measured on the balance, unless the laboratory restricts use of the balance to a constant single weight measurement.

The verification weights do not have to be calibrated weights but they must be weighed on the same day that a calibration, using calibrated weights, is performed.

4.2.2 Mechanical Pipettes/Dispensers/Dilutors

Daily or as-used verifications are performed by dispensing a measured volume to a tared balance and recording the weight (corrected for temperature and pressure). For adjustable dispensing devices, this procedure is performed at more than one volume.

4.2.3 Syringes

While syringes generally come with certificates from an ISO 9000 registered company, this certificate in itself is not sufficient evidence of on-going integrity of the syringe.

Accredited and applicant laboratories must have procedures in place to ensure the integrity of the syringes.

As a minimum, syringes must be identified and there must be procedure in place to ensure the integrity of the syringes. Procedures include, but are not limited to the following:

- Small volume syringes (<25 uL) (that will include both syringes used for standard preparation and sample introduction for the GC etc...) can be verified indirectly through the analysis of surrogate or internal standard; and,
- Larger syringes can be calibrated by repeated measurements using a traceable balance, and verified at a frequency adequate to identify problems.

5.0 REFERENCES

The following documents govern in the interpretation and application of this policy:

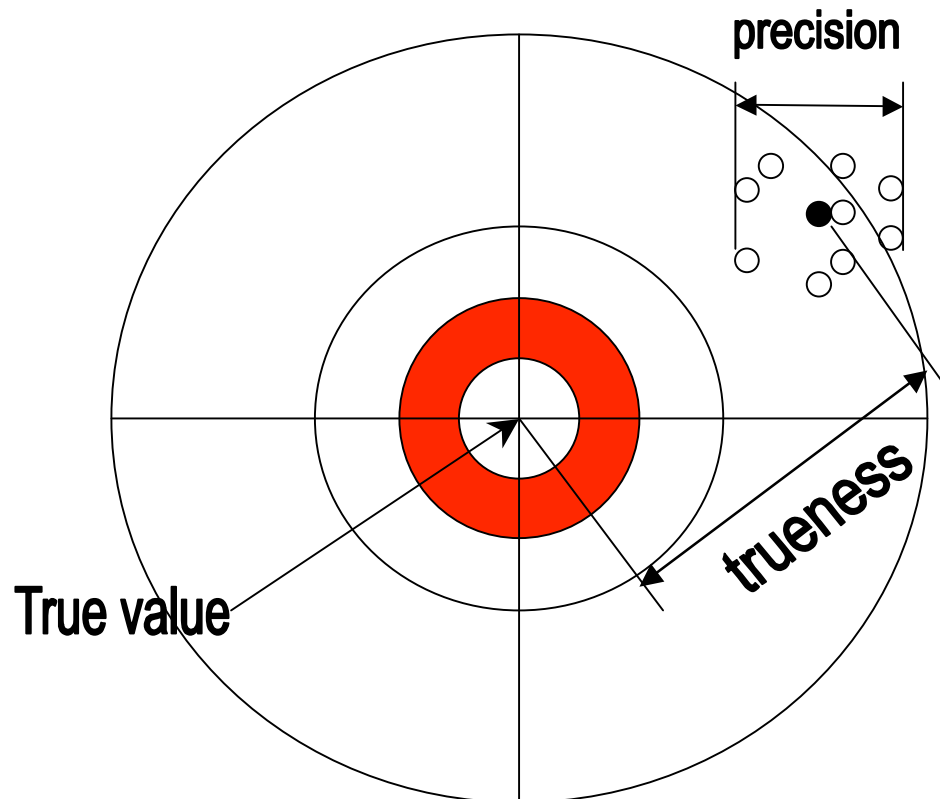
- Guide to the Uncertainty of Measurement (GUM);
- Vocabulaire internationale de metrologie (VIM);
- ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories;
- ILAC P10: ILAC Policy on the Traceability of Measurement Results
- CALA P19 - CALA Measurement Uncertainty Policy;
- CALA T27 - CALA ISO/IEC 17025 Handbook; and
- CALA P07 - CALA Interpretations of Requirements in ISO/IEC 17025.

APPENDIX A: GUIDANCE

A.1 Uncertainty and Traceability

Traceability is related to the concept of Uncertainty of measurement.

This diagram provides demonstration of their relation.



This diagram shows a series of results as the small white dots. They are not the same as the actual value one would get if we lived in a perfect world. This perfect or true value is represented by the centre of the target.

The black dot represents the average of all the results generated. It is not a result itself. It is also called the *mean* or *average* of the set of generated results. If a laboratory has produced a set of results from one large sample, then they may report this average as representative of the whole set.

Whether a laboratory reports a single result or the mean (average) of a set of results, the considerations for reporting uncertainty are the same in all cases:

- Accuracy: *Accuracy*, is a qualitative term only. It refers only to the concept of closeness to a true value. If one considers only the numbers, then one might examine the quantitative equivalent considerations. These are *trueness* and *precision*;
- Trueness: *Trueness* is how far the group of white dots is from the true value. Think of it as the distance from the true value to the black dot (mean);
- Precision: *Precision* is how dispersed the group of white dots are from each other and from the black dot (dispersion).

Note: It is important to understand that trueness and precision are independent of each other. One has nothing to do with the other.

- Bias: While the distance from the black dot to the centre of the target is a representation of how close the set of results came to the true value, the direction of the black dot from the true value can also be known as *bias*.

A.2 Need for Traceability

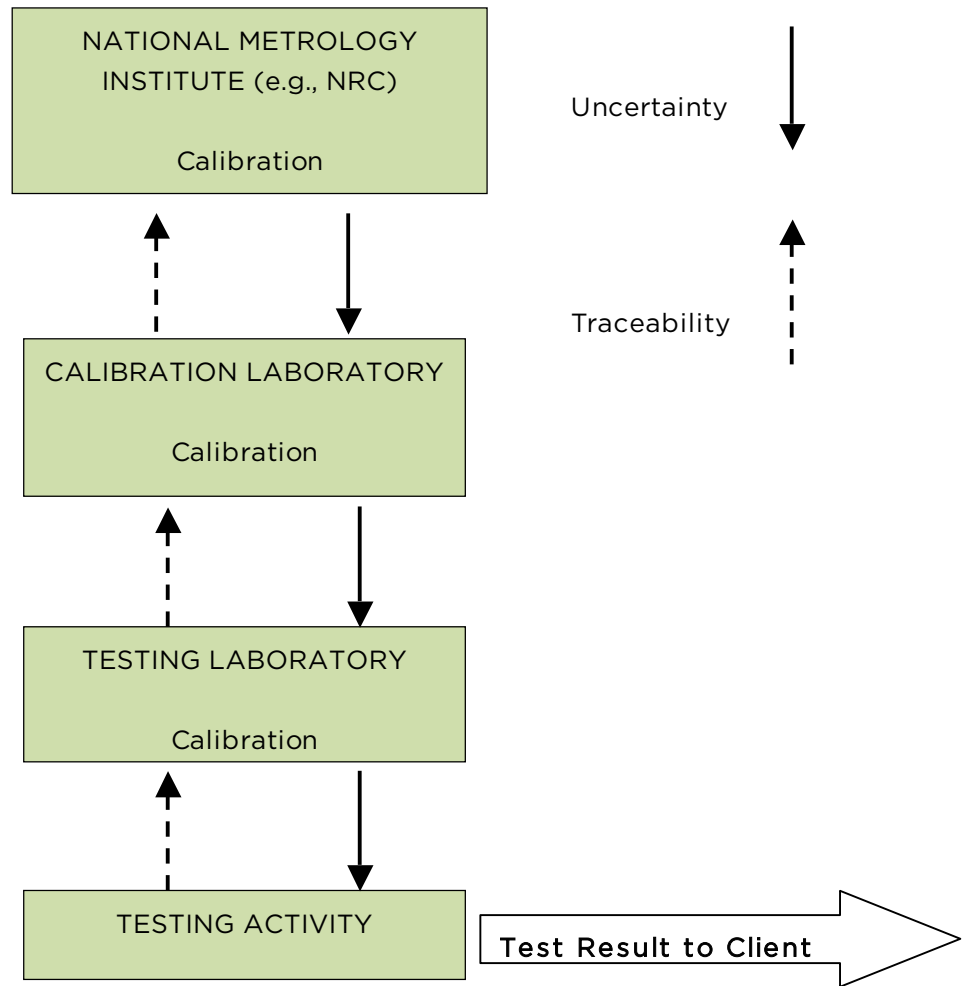
Traceability of the measurement is required to estimate the uncertainties associated with that measurement. See CALA P19 - *CALA Measurement Uncertainty Policy*. Uncertainty of any measurement is required in order to establish the confidence that an interpreter of results can have in it.

Traceability involves the competent propagation of uncertainties all along the chain of measurement to the test result produced by a testing laboratory. See the diagram on the following page. If uncertainties have not been propagated to the actual test result, the result is not traceable. If it is not traceable, then its precision and uncertainties may appear OK, but its trueness will always be suspect.

At the same time, uncertainties established along the traceability chain are the basis for the establishment of traceability of the measurement. The only property of a measuring instrument that counts, in considering traceability, is uncertainty. Test results, in order to be traceable, must be conducted using traceable instruments only.

Only those instruments that have been competently compared to others of known uncertainty (calibrated) can have their contribution to the overall uncertainty of the measurement objectively examined. When this condition is met, the measurement is considered traceable. If the instruments are not traceable, then the test result is not traceable.

A.2.1 What does traceability look like?



At the top of this diagram are all of the National Metrology Institutes (NMIs) that are responsible in each nation for quantifying specific parameters for use within their nation. Most NMI's have signed a multilateral recognition agreement based on the demonstration of competence (e.g., accreditation against ISO/IEC 17025).

The first job of an NMI is to characterise a parameter, such as *mass* or *temperature*, to a specific level of uncertainty. They propagate this uncertainty in support of competent measurements. This affects legal measurements (butcher weigh scales and gas pumps) as well as other fields of science requiring competent measurement.

Each NMI has the ability to conduct measurements with very small uncertainties. They are also able to calibrate the instruments from calibration laboratories seeking to establish traceability to the NMI. This is the start of the traceability chain for a testing laboratory.

Calibration, Traceability and Uncertainty are all required at any point in the traceability chain. None of these are deemed to be present unless ALL are present.

A.3 Implementation of this Policy in Accredited Laboratories

This policy means three things to CALA laboratories. First, it requires CALA laboratories to make use of measurement instruments, whose measurement traceability goes all the way back to an international standard (the SI) through a national measurement laboratory (e.g., NIST or NRC).

Second, it means that CALA laboratories must know how to spot the signs that an instrument is traceable or not.

Third, it means that CALA laboratories must understand the following simple relationship. All three of these components must exist at every level in the traceability chain in order for the final test result to be traceable.

**NO CALIBRATION
= NO UNCERTAINTY
= NO TRACEABILITY**

A.3.1 The Significance Test

Clause 5.6.1 of ISO/IEC 17025 states:

“All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established programme and procedure for the calibration of its equipment.”

Significance can be established using an approach that compares results from a simple statistical expression.

Any number, x , that is one third or less than another, y , will tend to have no significant effect on the outcome of the square root of the sum of their squares:

$$z = \sqrt{x^2 + y^2}$$

If, $x = 1.0$ and $y = 3.0$, then $z = 3.16$ if x is included in the expression and 3.0 if it is not. The difference is approximately 5%, a relatively insignificant difference when considering uncertainties.

Any number, x , that is one tenth or less than another, y , will tend to have negligible effect on the outcome of the square root of the sum of their squares.

If, $x = 1.0$ and $y = 10.0$, then $z = 10.05$ if x is included in the expression and 10.0 if it is not. The difference is approximately 0.5%, a *negligible* difference when considering uncertainties.

The following three examples may be used by laboratories to determine which of their instruments meet the requirement for significant effect in their calibration program.

- Example 1: If the uncertainty of an instrument is smaller than one-tenth of the largest contributor in the estimation of uncertainty for all tests affected by that instrument, then the laboratory has evidence to increase the period of calibration from one to two years or more, decreasing its frequency of calibration.
- Example 2: If the uncertainty of an instrument is between one tenth and one-third of the largest contributor in the estimation of uncertainty for all tests affected by that instrument, then the laboratory must maintain the period of calibration at one year.
- Example 3: If the uncertainty of an instrument is larger than one-third of the largest contributor in the estimation of uncertainty for all tests affected by that instrument, then the laboratory has evidence to decrease the period of calibration to less than one year; for example every six months.

The choices to a laboratory are the following, and they depend on the significance of the contribution of the instrument to the overall uncertainty of the desired test result as described by the examples above:

- When instrument performance is very much better than the requirement, the laboratory can reduce the calibration frequency (extend the cycle time). See example 1 above;
- When performance is at the same level as requirement, the calibration frequency must be increased. See example 3 above; or,
- When the laboratory does not know, they must calibrate that equipment once per year. See example 2 above.

In general, the only instruments in a typical analytical laboratory that require traceability through contracts with an external calibration laboratory are analytical balance calibration and thermometer calibration. Volume (e.g., pipettes) must also be traceable but their traceability is usually linked to mass (1.0 mL of water weighs 1.0 g at standard temperature and pressure).

Chemicals and standards purchased for the purpose of instrument calibration must also be traceable but their traceability is ensured through proper analytical methods and proper procurement procedures. A good description of chemical traceability can be found in *Traceability in Chemical Measurements* (Eurachem 2003).

A.3.2 Balances

A.3.2.1 Verification

Using a minimum of two weights that are within the weights typically measured on the balance allows the laboratory to demonstrate stability of operation of the balance over the whole range normally used.

The documented procedure for the verification process should include the use of appropriate weights (e.g., stainless steel), the storage and handling of the verification weights, and the acceptance criteria.

If the verification weight (mass) is to be subsequently used to calibrate balances, it must be calibrated and have an uncertainty associated with it.

A.3.2.2 Internal Calibration Using Historical Data

Historical daily or as-used verification data can be used to develop standard deviations for calibration provided all the requirements for calibration are met for each verification reading. This includes, but is not limited to, ensuring:

- that the laboratory documents their verification procedure to include all of the same requirements for the performance of a calibration but with as few as one reading on each day of verification;
- that a statistically valid number of readings are used in the determination of the standard deviations for the calibration;
- that the person conducting the verification has been properly trained on the procedure used;
- that they can competently propagate uncertainties from the reference standard (calibrated weights) to the working instrument; and,
- that they use calibrated weights that meets the requirements of ISO/IEC 17025 for this purpose.

For both A.3.2.1 and A.3.2.2, there is an unbroken chain of uncertainty and traceability between the NMI and the working balance.

A.3.3 Thermometers

As with the balances, a laboratory can demonstrate traceability of their temperature measurements in a couple of ways.

A.3.3.1 External Calibration of all Thermometers

A laboratory may opt to send all working thermometers to an accredited laboratory for calibration at an established frequency (e.g., annually). This is by far the easiest way to ensure traceability of all critical thermometers but can be costly and requires the purchase of more thermometers than are used on a daily basis in order to ensure the availability of calibrated thermometers when others are being calibrated.

A.3.3.2 External Calibration of Reference Thermometers with Internal Calibration of Working Thermometers

A laboratory may decide to maintain a limited number of thermometers that are sent to an accredited calibration laboratory on a scheduled basis (e.g., annually). The lab may then use these reference thermometers to calibrate working thermometers. The internal calibration must use an accepted protocol, such as NIST Special Publication 1088 – *Maintenance, Validation and Recalibration of Liquid-in-Glass Thermometers*. The internal calibration procedure involves replicate measurements and the propagation of uncertainty. The frequency of calibration of liquid-in-glass thermometers may be decreased provided a set of conditions are met; for details on the conditions and procedures, see NIST Special Publication 1088.

A.3.4 Volumetric Measurements

A.3.4.1 Pipettors/Dispensers/Dilutors

As with balances, dispensing devices must be calibrated upon receipt and at an established frequency (e.g., annually) and verified on a daily or as-used basis.

Dispensing devices may be sent to an accredited calibration laboratory for calibration but this is often cost prohibitive. Alternately, the laboratory may perform an internal calibration following a generally accepted procedure such as those provided by Troemner, Mettler-Toledo, and Rainin. These procedures generally involve the repeated weighing of dispensed volumes of water, corrected for standard temperature and pressure. For adjustable dispensing devices, this procedure is performed at more than one volume. The procedure will generally include 10 measurements at the low end and 10 at the high end of the dispensing range. Acceptable performance (precision) is based on the precision required for the piece of dispensing equipment. Historical daily or as-used verification data can be used to develop standard deviations for calibration provided all the requirements for calibration are met for each verification reading. This includes, but is not limited to, ensuring:

- that the laboratory documents their verification procedure to include all of the same requirements for the performance of a calibration but with as few as one reading on each day of verification;
- that a statistically valid number of readings are used in the determination of the standard deviations for the calibration;
- that the person conducting the verification has been properly trained on the procedure used;
- that they can competently propagate uncertainties from the reference standard (device) to the working instrument; and
- that they use a calibrated balance that meets the requirements of ISO/IEC 17025 for this purpose.

A.3.5 Selecting a Calibration Laboratory

Traceability means that all of the comparisons back along the Calibration chain to the national measurement laboratory were done by competent organisations (calibration laboratories). The competence of a calibration laboratory is most easily established by ensuring that the calibration laboratory is *accredited* to ISO/IEC 17025 for the task. For example, the following table represents a sample Scope of Accreditation for an accredited calibration laboratory:

Measurement Parameter	Range of Measurement	Related Uncertainty
Temperature	0.01 - 140.01 degrees C	+/- 0.003 degrees C
Volume	0.05 - 200.00 Litres	+/- 0.005 ml
Mass, Length, etc		

An accredited calibration laboratory that is recognised by the CALA will normally be found on one of the following websites:

- SCC/CLAS - <http://inms-ienm.nrc-cnrc.gc.ca>
- NVLAP - <http://ts.nist.gov/ts/htdocs/210/214/scopes/programs.htm>
- A2LA - <http://www.a2la.org/dirsearch/search9.cfm>
- IAS - http://www.iasonline.org/Calibration_Laboratories/CL.html
- L-A-B - http://www.l-a-b.com/search_lab_documents.htm
- ACLASS - <http://www.aiclasscorp.com/Directory/tabid/113/Default.aspx>

This list is not exhaustive as CALA recognises other laboratory accreditation bodies, but these are the ones closest to you, the CALA laboratory.

A.3.5.1 How to determine if a calibration certificate was provided by a Competent Calibration Lab?

The easiest way is to look for the logo or name of one of the accreditation bodies cited above on the calibration certificate. If it is not there, then the calibration service provider is probably not accredited. Remember, a service provider that is only registered (or certified)

to ISO 9000 (or other management system standard) is not considered a technically competent calibration service provider.

From the rules which govern the accreditation of ISO 9000 registrars, IAF Guide 2, Clause 3.5.8: Certification/registration bodies may be accredited to certify/register the quality management systems of test and calibration laboratories, but it should make it clear to the client that such certification/registration is not equivalent to accreditation of the testing or calibration laboratory. A certification/registration body shall not permit its marks to be applied to laboratory test and calibration reports, as such reports are deemed to be products in this context.

An organisation that puts an ISO 9000 registration logo on a calibration certificate is in breach of their certification. The registrar is in breach of their accreditation as a registrar and the accrediting body is in breach of the international agreements which permit mutual recognition of registrar accreditation.

The second way to spot a lab with questionable competence is by the absence of an uncertainty statement for each range of measurement within the specific measurement parameter of the instrument associated with the calibration certificate. Remember two things when dealing with calibration service providers:

- You went to the trouble to have your lab's technical competence recognised through accreditation, so why would you wish to deal with a laboratory that won't do the same as a calibration laboratory?
- Your laboratory provides test results. That is the principle product of a testing laboratory. The principle product of a calibration laboratory is uncertainty as it relates to measuring instruments (for a specific measurement parameter, within a specified range of measurement).

If these are not on the calibration certificate as a minimum, then the certificate will not meet the traceable calibration requirements.

Before purchasing a traceable thermometer or calibration certificate, you may be able to obtain from your potential supplier an example of their calibration certificates. This will allow you to review the calibration certificate and if you have any concerns about whether you are meeting the traceability and calibration requirements, you can get answers from your supplier before you purchase the item or service.

Note: The cost for traceability is usually higher than the non-traceable calibration, so if you are choosing between levels of service and are paying the lowest price for a calibration, it's probably not traceable.

A.3.6 If an Accredited Calibration Laboratory is not Available for Specific Measurements

There are many gaps in the measurement capability of competent calibration infrastructure in North America. Your first step is to let CALA know that there is an unmet calibration need for the specific measurement. CALA will let the NRC know. Over time, these unmet needs should be filled.

If you have any questions on this, or any other policy associated with the assessment of your laboratory to the requirements of the CALA Accreditation Program, please feel free to contact CALA at (613) 233-5300.

APPENDIX B: TERMS AND DEFINITIONS

- Calibration: Calibration is a comparison of measurements between two standards or measurement devices. It involves the competent propagation of uncertainties from the instrument or standard whose measurement characteristics are known and traceable to the SI, to an instrument or standard whose measurement characteristics are to be quantified through this comparison.
- Calibration Curve: This applies to analytical laboratory instrumentation. The term defines the relation between analyte concentration and instrument response.
- Control Standard: A standard used as a basis for comparison with calibration standards, prepared independently from the calibration standards, and which undergoes sample processing identical to that carried out for the calibration standards.
- Reference Material (RM): Material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to the materials. (ISO/IEC Guide 43-1)
- SI (Système International d'Unités): The name (*International System of Units*) adopted by the 11th General Conference on Weights and Measures (1960) for the recommended practical system of units of measurement. The **base units** are a choice of seven well-defined units: the metre, the kilogram, the second, the ampere, the Kelvin, the mole, and the candela.
- Traceability: A property of the result of a measurement or the value of a standard whereby it can be related, with a stated uncertainty, to stated references, usually national or international standards, through an unbroken chain of comparisons. (ISO Guide 30).
- Trueness: The closeness of agreement between the average value obtained from a large series of test results and an accepted reference value. (ISO 3534-1, 3.12).
- Uncertainty of Measurement: Parameter that characterizes the dispersion of the quantity values that are being attributed to a measurand, based on the information used. (VIM)
- Verification: Confirmation through examination of a given item and provision of objective evidence that it fulfils specified requirements. [modified from ISO 9000:2005, item 3.8.4]

A procedure normally associated with the acquisition of data regarding an instrument to provide some indication as to whether it is operating within expected tolerances. For example, calibrated weights may be placed on a balance and the reading can provide some indication as to whether the balance is operating within expected tolerances. This operation should not be confused with calibration.

Verification does not establish traceability. Verification seeks only to determine whether or not the instrument is operating within its expected tolerances. It is not a method of propagating uncertainties, which is the core issue in a *calibration*.

Note that manufacturer's tolerances, as provided in data sheets and instrument manuals, will use the same method of expression as an uncertainty, such as +/- 3% or +/- 4 grams. These are still only *tolerances* and should not be confused with *uncertainties* associated with each range of measurement for the instrument as *established through calibration*.